

**EPA REGISTRATION NUMBER 53053-27 – VOL. 2**

## Leavy, Karen

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**From:** Cinda Bell <[cbell@scireg.com](mailto:cbell@scireg.com)>  
**Sent:** Thursday, June 21, 2018 9:56 AM  
**To:** Leavy, Karen  
**Cc:** Miederhoff, Eric  
**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27  
**Attachments:** AM 3651 P, label, clean, 6-20-18.pdf

Good morning,

Attached is the clean PDF label as requested.

To address Eric's public health use rate comment from yesterday, I should have clarified that we were referring to the rate on page 5 of the ProShield label where the rate is 2 fl. oz. per cup. The rate of 8 oz. per gal. under dipping/soaking does not tell you how much fabric to treat so you cannot calculate how much is on the fabric to compare.

Kind regards,  
Cinda

**From:** Leavy, Karen [<mailto:Leavy.Karen@epa.gov>]  
**Sent:** Thursday, June 21, 2018 8:25 AM  
**To:** Cinda Bell  
**Cc:** Miederhoff, Eric  
**Subject:** FW: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Good Morning Cinda,

Can you provide me with pdf, clean copy of the proposed product labeling instead of a red lined WORD version of the proposed product labeling?

KML

**From:** Cinda Bell [<mailto:cbell@scireg.com>]  
**Sent:** Friday, June 15, 2018 12:51 PM  
**To:** Miederhoff, Eric <[Miederhoff.Eric@epa.gov](mailto:Miederhoff.Eric@epa.gov)>; Leavy, Karen <[Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov)>  
**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Hi Eric / Karen,

The attached label contains the trimethoxysilyl quats and has laundry uses on page 8. Does that help to add the laundry use to this label? Also, what do we need to do to get the algae and slime control in cooling and process waters use added to the label?

A couple comments on the revised label.

- We did not include the ATCC numbers as we do not have the supporting data.
- The dilution rates (2.0 fl. oz. per gal. of water) are the same for spray, mop and bucket, and soaking applications. The label rate of 0.6 oz. product to 1 to 2 gallons of water is correct for the laundry use. We deleted soaking the laundry.

Please let me know if you have any questions.

Kind regards,  
Cinda

**From:** Miederhoff, Eric [<mailto:Miederhoff.Eric@epa.gov>]  
**Sent:** Wednesday, June 13, 2018 4:33 PM  
**To:** Cinda Bell; Leavy, Karen  
**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Hi Cinda,

The product you referenced does not contain the trimethoxysilyl quat that 53053-27 does. The silyl quats are assessed separately from ADBAC and DDAC, and so the uses for those two chemicals do not support uses for the silyl quats.

Regards,

Eric Miederhoff  
Product Manager, Team 31  
Regulatory Management Branch I  
Antimicrobials Division  
Office of Pesticide Programs  
Environmental Protection Agency  
703-347-8028

**From:** Cinda Bell [<mailto:cbell@scireg.com>]  
**Sent:** Tuesday, June 12, 2018 11:26 AM  
**To:** Leavy, Karen <[Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov)>  
**Cc:** Miederhoff, Eric <[Miederhoff.Eric@epa.gov](mailto:Miederhoff.Eric@epa.gov)>  
**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Hi Karen,

Attached is a label that has the laundry bacteriostatic and cooling towers and processors uses. Why are these considered new uses? The data matrix submitted with this amendment covers all the data to support these uses.

Kind regards,  
Cinda

**From:** Leavy, Karen [<mailto:Leavy.Karen@epa.gov>]  
**Sent:** Monday, June 11, 2018 11:48 AM  
**To:** Cinda Bell  
**Cc:** Miederhoff, Eric  
**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Good Morning Cinda,

What are the MRID Nos., titles of the actual studies, and/or cited studies that support the laundry bacteriostatic and cooling towers and processors use cited?

KML

**From:** Cinda Bell [mailto:[cbell@scireg.com](mailto:cbell@scireg.com)]

**Sent:** Monday, June 11, 2018 11:34 AM

**To:** Leavy, Karen <[Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov)>

**Subject:** RE: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Hi Karen,

Why do we have to delete the laundry bacteriostatic and cooling towers and processors uses if they are new uses?  
Seems like the data covers the uses.

Kind regards,  
Cinda

**From:** Leavy, Karen [mailto:[Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov)]

**Sent:** Thursday, June 07, 2018 10:00 AM

**To:** Cinda Bell

**Cc:** Miederhoff, Eric; OPP AD Ombudsman

**Subject:** Re: EPA Completed Action Predecisional Letter and Mocked up labeling for EPA Reg. No. 53053-27

Good Morning Cinda,

Attached is the a copy of the Predecisional Letter for EPA Reg. No. 53053-27. In additional labeling with revisions/comments is also attached above.

KML



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 7, 2018

Ms. Cinda Bell  
Regulatory Agent for,  
IndusCo. Ltd.  
2319 Joe Brown Drive  
Greensboro, NC 27405

SUBJECT: EPA Registration Number: 53053-27  
Product Name: EnviroSystems ProShield 365I D  
Application Date: February 8, 2018  
Decision Number: 538238

The Agency has completed its review and assessment of your application as pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label as per the efficacy review and attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

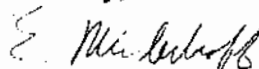
- (a) Applicant agrees to all of the terms associated with the attached label and makes necessary changes as per the efficacy review; or
- (b) Applicant does not agree to one or more of the terms of the attached label and efficacy review by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703) 308-6237 or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Sincerely,

A handwritten signature in cursive script, appearing to read "E. Miederhoff".

Eric Miederhoff  
Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

# PROCESSING REQUEST

Reg # 53053-27

Decision # 538238

Description: PRIA Labeling Amendment

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

X Dated: 07/02/18

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD

Phone: 308-6237

Date: 07/02/18



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 2, 2018

Ms. Cinda Bell  
Regulatory Agent for,  
IndusCo., Ltd.  
2319 Joe Brown Drive  
Greensboro, NC 27405

Subject: PRIA Label Amendment – To add *Pseudomonas aeruginosa* claims  
Product Name: EnviroSystems ProShield 3651 D  
EPA Registration Number: 53053-27  
Application Date February 8, 2018  
Decision Number: 538238

Dear Ms. Bell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

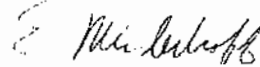
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.



Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Sincerely,



Eric Miederhoff  
Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure

**EnviroSystems® ProShield® 3651 D**  
**DISINFECTANT and ANTIMICROBIAL AGENT**  
**A Silicone Quaternary Ammonium Salt**

**Active Ingredients:**

3-(trimethoxysilyl)propyldimethyl octadecyl ammonium chloride.....	35.60%
n-alkyl (60%C14, 40%C12, 10%C16) dimethyl benzyl ammonium chloride .....	6.40%
Octyl decyl dimethyl ammonium chloride .....	4.80%
Dioctyl dimethyl ammonium chloride .....	1.92%
Didecyl dimethyl ammonium chloride .....	2.88%
<b>Other Ingredients:</b> .....	48.40%
<b>Total</b> .....	100.00%

Contains over 6% Methanol

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER ☠ POISON**

NET CONTENTS: 2, 4, 8, 16, 20, 22, or 36 fluid oz.; 1, 5, 55, 150, or 300 gal

Lot No.:

EPA Reg. No.: 53053-27

EPA Est. No.: 53053-NC-01

**ACCEPTED**

**07/02/2018**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 53053-27

**FIRST AID**

Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

**IF INHALED:**

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:**

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.
- Methanol may cause blindness

Page 1 of 6  
July 2, 2018

**IF ON SKIN OR CLOTHING:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**NOTE TO PHYSICIAN**

Probably mucosal damage may contraindicate the use of gastric lavage.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER! Corrosive:** Methanol may cause blindness. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield) and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**PHYSICAL OR CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame. De-activation of EnviroSystems® ProShield® 3651 D can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of EnviroSystems® ProShield® 3651 D.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Deactivation may be required during clean up if a spill occurs. Deactivation of EnviroSystems® ProShield® 3651 D can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of EnviroSystems® ProShield® 3651 D.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

For use in homes, offices, institutions (schools, universities, daycare centers, churches, correctional facilities), medical related facilities (laundries, clinics, dental offices, health care facilities, hospitals, medical offices, nursing homes), public facilities (airports, transportation terminals, bars, convenience stores, athletic facilities, locker rooms, barber shops, salons, hotels, public restrooms, playgrounds), transportation (airplanes, ambulances, boats, buses, campers, cars, emergency vehicles, ships, taxis, trains, trucks) and animal facilities (animal laboratories, farms, kennels, pet shops, zoos). This product may not be used on food contact surfaces.

EnviroSystems® ProShield® 3651 D controls odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* (spray application only).

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [This product can be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.]

(OR)

[This product is not for use on medical device surfaces to the proposed, product labeling.]

#### Application Instructions:

Dilute 2.0 fl. oz. in one gallon of water (1 gallon of EnviroSystems® ProShield® 3651 D per 64 gallons of water)

For spray application, dilute EnviroSystems® ProShield® 3651 D in water and mix well. Using a trigger pump sprayer, spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. The surface should remain visibly wet for 10 minutes then wipe surface dry.

For mop and bucket application, dilute EnviroSystems® ProShield® 3651 D in a bucket and mix well. Mop area thoroughly.

For soaking application, dilute EnviroSystems® ProShield® 3651 D in a container and mix well. Soak item for 10 minutes then wipe dry.

Laundry Bacteriostat: (Not for use in the state of California) Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. EnviroSystems® ProShield® 3651 D provides cleaning properties against odor-causing bacteria for laundered items such as diapers, hospital and institutional linens, and athletic clothing. Use 0.6 ounces EnviroSystems® ProShield® 3651 D per 100 pounds of dry fabric. Dilute the product in one to two gallons of water and add to the wash wheel in the final rinse. Retreat fabric after each washing. Dry fabric prior to use.

## OPTIONAL LANGUAGE and MARKETING CLAIMS

EnviroSystems® ProShield® 3651 D is an effective disinfectant against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

EnviroSystems® ProShield® 3651 D is effective against odor causing bacteria, bacteria that cause staining and discoloration, fungi (mold and mildew), and algae.

EnviroSystems® ProShield® 3651 D may be used for treatment of the following hard nonporous surfaces to impart disinfection (*Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*), bacteriostatic/fungistatic/algaestatic, and deodorizing activity: Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators.

MOLD, MILDEW, ODOR PROTECTOR, ODOR INHIBITOR

Concentrate (Concentrated)

Bactericidal

Deodorizes (Deodorizer)

Disinfects (Disinfectant)

For Hospital, Institutional, Industrial and Home Use

A Disinfectant for use in Hospitals

Hospital Disinfectant

EnviroSystems® ProShield® 3651 D can be used

- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps.
- as a broad-spectrum disinfectant in Ultrasonic Baths (Ultrasonic cleaning units).
- for cleaning and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces. Will not cause swelling of transducer membrane or harm compressor plates.
- Veterinary Practices, Animal Care, Animal Laboratory and Farm Premise applications.
- for swine premise sanitation on/in hauling equipment, loading equipment, farrowing barns and areas, nursery, blocks, creep areas.
- for farm premise sanitations on floors, walls, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, and other facilities and fixtures occupied or traversed by animals.
- to clean and disinfect (manicure)(nail)(salon)(barber) tools and instruments: combs, brushes, scissors, blades, and manicure instruments.

- on (to clean and disinfect) nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.
- on (to clean and disinfect) wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* in hospitals and other medical facilities.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective against odor causing bacteria and fungi (mold and mildew) that cause offensive odors on hard, non-porous surfaces.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective against odor causing bacteria in the kitchen and bathroom.

EnviroSystems® ProShield® 3651 D is an antimicrobial agent effective in controlling mold and mildew, and inhibiting the growth of mold and mildew.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, disinfects hard, non-porous surfaces and kills *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

EnviroSystems® ProShield® 3651 D, an antimicrobial agent, can be used in and around bathtubs and showers stalls to prevent the growth of mold and mildew.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of odor causing bacteria.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D provides an invisible barrier to inhibit the growth of algae.

EnviroSystems® ProShield® 3651 D prevents deterioration caused by odor causing bacteria and fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D resists development of odor causing bacteria.

EnviroSystems® ProShield® 3651 D resists development of stains and discoloration due to odor causing bacteria.

EnviroSystems® ProShield® 3651 D resists development of stains due to fungi (mold and mildew).

EnviroSystems® ProShield® 3651 D resists stains due to algae.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Containers 1 gallon or less: Wastes resulting from the use of this product may be disposed of on site.

**Container Disposal:** (plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. (metal) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (glass) Triple rinse (or equivalent), then dispose of in a sanitary landfill or by approved State and local procedures.

Container 1 gallon or less: Securely wrap original container in several layers of newspaper and discard in trash.

### IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

IndusCo, Ltd. warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this label when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

INDUSCO, LTD. SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

IndusCo, Ltd.  
2319 Joe Brown Drive  
Greensboro, NC 27405



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

Date: 6/1/2018

Subject: Efficacy Review for ENVIROSYSTEMS PROSHIELD 3651D,  
EPA Reg. No. 53053-27  
(DP Barcode: 446029, Submission: 1015476)

From: Samantha Collins  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) *Kristen Willis*

To: Eric Miederhoff, Team 31 / Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: INDUSCO LTD

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
3-(trimethoxysilyl)propyldimethyl octadecyl ammonium chloride .....	35.6%
n-alkyl (60%C14, 40%C12, 10%C16) dimethyl benzyl ammonium chloride .....	6.40%
Octyl decyl dimethyl ammonium chloride .....	4.80%
Dioctyl dimethyl ammonium chloride .....	1.92%
Didecyl dimethyl ammonium chloride .....	2.88%
<u>Other Ingredients</u> .....	48.4%
<u>Total</u> .....	100.0%



## **I BACKGROUND**

**Product Description (as packaged, as applied):** Liquid concentrate

**Submission type:** Label amendment

**Currently registered efficacy claim(s):** General disinfectant (bactericidal) for use on hard, non-porous surfaces.

**Requested action(s):** Add hard, non-porous surface spray disinfectant claims at a 10-minute contact time against *Pseudomonas aeruginosa* (ATCC 15442).

**Documents considered in this review:**

- Letter from applicant to EPA dated February 8, 2018
- Data Matrix (EPA Form 8570-35)
- 1 efficacy studies (MRID 50523801)
- Proposed label dated 02/08/2018
- Confidential Statement of Formula (EPA Form 8670-4) dated 08/06/2001.

## **II PROPOSED DIRECTIONS FOR USE**

"Dilute 2.0 fl. Oz. in one gallon of water (1 gallon of EnviroSystem ProShield 3651D per 64 gallons of water)

For spray application, dilute EnviroSystem ProShield 3651D in water and mix well. Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand for 10 minutes then wipe the surface.

For mop and bucket application, dilute EnviroSystem ProShield 3651D in a bucket and mix well. Mop area thoroughly.

For soaking application, dilute EnviroSystem ProShield 3651D in a container and mix well, soak item for 10 minutes then wipe dry.

### III STUDY SUMMARIES

1.	MRID	50523801	Study Completion Date:	11/07/17			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Accuratus, A24210					
Test organism(s)		<i>Pseudomonas aeruginosa</i> (ATCC 15422)					
<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+							
Test Method		AOAC Germicidal Spray Method					
Application Method		Liquid Spray					
Test Substance Preparation	Name/ID	ProShield 3651 D					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	NC17-0921A, NCI 7-0921B and NC17-0307					
	Preparation	Tested concentration: LCL Dilution: 2oz./gallon Diluent: deionized water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Glass Slides, 60					
Test conditions		Contact time	10 minutes	Temp	20°C	RH	44%
Neutralizer		Lethen broth with 0.14% lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

### IV STUDY RESULTS

#### Disinfection – Bactericidal Efficacy

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average log <sub>10</sub> CFU/Carrier
		Batch J061441	Batch J092241	Batch J110941	
10 minute contact time, purified water, 5% soil load, 2 oz/gallon					
50523801 (11/07/17)	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	0/60	5.53

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50523801	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, 2 oz product per gallon of water	10 minutes	5%	deionized water	• <i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes

## VI LABEL COMMENTS

Label Date- 02/08/2018:

1. The proposed label claims that the product, ENVIROSYSTEMS PROSHIELD 3651D, when diluted at 2 oz. per gallon of water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

*Pseudomonas aeruginosa* (ATCC 15442)

These claims are acceptable as they are supported by the submitted data.

2. Make the following changes to the proposed label:
  - a. In the use-directions on the proposed label, registrant must clearly distinguish that claims against *Pseudomonas aeruginosa* (ATCC 15442) are only relevant for the spray application. AOAC Germicidal Spray Method does not encompass use-dilution claims.
  - b. On page 3 of the proposed label, revise the directions for spray application to read as follows: "Using a trigger pump spray, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. The surface should remain visibly wet for 10 minutes then wipe surface dry."
  - c. On page 4 of the proposed label, remove the claim "Germ Killer", to make a qualified "germ" claim the product must have qualified label claims against one of the two classes of additional organisms (fungi or virus). Please see the following for additional information: <https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>
  - d. On page 5 of the proposed label, remove all claims of sanitization. No data was submitted to qualify this claim. Registrant may replace "sanitize" with "cleaning".
  - e. On page 5 and 6 of the proposed label, remove all "germ" claims. See (b) above.
  - f. The bacterial strain identification/collection number (e.g ATCC) should be added to all bacteria listed on label.

Note to the Reviewer: The label states "contains over 6% methanol" which is toxic for a household use. However, the chemical is not listed as an inert on the CSF. Please check with RASSB and Chemistry that this is acceptable and within current standards.

# DATA PACKAGE BEAN SHEET

Date: 01-Mar-2018

Page 1 of 3

Decision #: 538238

DP #: (446029)

PRIA

Parent DP #:

Submission #: 1015476

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 53053-27 - ENVIROSYSTEMS PROSHIELD 3651 D

Company: 53053 - INDUSCO LTD

Risk Manager: RM 31 - Eric Miederhoff - 703-347-8028 Room# PY1 S-8217

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date:

PRIA Due Date: 02-Jul-2018

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

Ingredients: See page 3

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 01-Mar-2018

Due Back:

DP Ingredient: See page 3

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 02-Jun-2018

Team Name: EET

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Technical Screen Review-please review the submitted AOAC Germicidal Spray Method data to add Pseudomonas Aeruginosa to the proposed product labeling.

PRIA, Action Code A570, Technical Screen Due Date 04/16/18, PRIA Due Date 07/02/18.

Data nor Administrative Materials are in Documentum.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number  IndusCo, Ltd. 2319 Joe Brown Dr. Greensboro, NC 27405	EPA Registration Number/File Symbol  53053-27
Active Ingredient(s) and/or representative test compound(s)  Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16) 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride	Date  2/8/18
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Antimicrobial	Product Name EnviroSystems ProShield 3651 D

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Cinda L. Bell</i>	Date 2/8/18	Typed or Printed Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W. WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date <u>2/8/18</u>		EPA Reg No./File Symbol 53053-27		Page 1 of 6	
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405		Product EnviroSystems ProShield 3651 D			
Ingredient Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

**Generic Data [EnviroSystems BioShield 7200 (EPA Reg. No. 53053-25)]**

	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	IndusCo, Ltd.	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	Innovative Chemical Technologies	OWN			
	IndusCo, Ltd.	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	Innovative Chemical Technologies	OWN			
	IndusCo, Ltd.	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
	Inhold, LLC	OWN			
IndusCo, Ltd.	OWN				
Inhold, LLC	OWN				
Inhold, LLC	OWN				
IndusCo, Ltd.	OWN				
Signature <u>Cinda L. Bell</u>		Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.		Date <u>2/8/18</u>	

Form Approved OMB No. 2070-0060  
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
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**DATA MATRIX**

Date <u>2/8/18</u>	EPA Reg No./File Symbol 53053-27	Page 2 of 6
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405	Product  EnviroSystems ProShield 3651 D	

**Ingredient** Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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**Generic Data [EnviroSystems BioShield 7200 (EPA Reg. No. 53053-25)]**

	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
	IndusCo, Ltd.	OWN	
	Inhold, LLC	OWN	
	IndusCo, Ltd.	OWN	
	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
			NA. The product does not contain an oxidizing or reducing agent.
	Inhold, LLC	OWN	
			NA. The product is not potentially explosive.
	IndusCo, Ltd.	OWN	
			NA. The product is not an emulsifiable liquid to be diluted with petroleum solvents.
	IndusCo, Ltd.	OWN	
Inhold, LLC	OWN		
Inhold, LLC	OWN		
Inhold, LLC	OWN		
Inhold, LLC	OWN		

Signature <u>Cinda L. Bell</u>	Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.	Date <u>2/8/18</u>
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**DATA MATRIX**

Date <u>2/8/18</u>		EPA Reg No./File Symbol 53053-27		Page 3 of 6	
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405		Product  EnviroSystems ProShield 3651 D			
Ingredient Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Generic Data [EnviroSystems BioShield 7200 (EPA Reg. No. 53053-25)]</b>					
		IndusCo, Ltd.		OWN	
		IndusCo, Ltd.		OWN	
		IndusCo, Ltd.		OWN	
		IndusCo, Ltd.		OWN	
		IndusCo, Ltd.		OWN	
		IndusCo, Ltd.		OWN	
Signature <i>Cinda L. Bell</i>		Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.		Date <u>2/8/18</u>	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

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**DATA MATRIX**

Date <u>2/8/18</u>	EPA Reg No./File Symbol 53053-27	Page 4 of 6
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405		Product  EnviroSystems ProShield 3651 D

Ingredient Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Generic Data [EnviroSystems BioShield 7200 (EPA Reg. No. 53053-25)]

	W.M Barr & Company, Inc. Nalco Diversified Technologies, Inc. Mason Chemical Company Goulston Technologies, Inc. Piedmont Chemical Industries, LLC American Chemistry Council Aegis Environments Spray Drift Task Force Coating Systems Laboratories, Inc. Unelko Corporation Sishield Technologies, Inc. Marinize Products, Inc. Jennico2 Inc. Duraban International Inc. American Mouldguard, Inc. BioSafe, Inc. NBS Technology, LLC Coating Specialists, LLC Vitec Global Limited Tile Media Properties, Inc. Abtech Industries, Inc. Coeus Technology, Inc. PureShield, Inc. As Filtration, LLC	PAY	

Signature <u>Cinda L. Bell</u>	Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.	Date <u>2/8/18</u>
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**DATA MATRIX**

Date <u>2/8/18</u>	EPA Reg No./File Symbol 53053-27	Page 5 of 6
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405		Product EnviroSystems ProShield 3651 D

Ingredient Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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**Product Specific Data**

	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
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	Inhold, LLC	OWN	
	Inhold, LLC	OWN	
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	Inhold, LLC	OWN	
	Inhold, LLC	OWN	

Signature <i>Cinda L. Bell</i>	Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.	Date <u>2/8/18</u>
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**DATA MATRIX**

Date <u>2/8/12</u>	EPA Reg No./File Symbol 53053-27	Page 6 of 6
Applicant's/Registrant's Name & Address IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405		Product  EnviroSystems ProShield 3651 D

Ingredient Bardac 208M (contains PC Codes 69105, 69149, 69165, and 69166) and EnviroSystems BioShield 7200 (contains PC Code 107401)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Inhold, LLC	OWN	
			Inhold, LLC	OWN	
			Inhold, LLC	OWN	
			Inhold, LLC	OWN	
			Inhold, LLC	OWN	
			Inhold, LLC	OWN	
			IndusCo, Ltd.	OWN	
			IndusCo, Ltd.	OWN	
			IndusCo, Ltd.	OWN	Submitted herein

Signature <i>Cinda L. Bell</i>	Name and Title Cinda L. Bell, Agent for IndusCo, Ltd.	Date <u>2/8/12</u>
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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 53053-27	2. EPA Product Manager Eric Miederhoff	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EnviroSystems ProShield 3651 D	PM# 31	
5. Name and Address of Applicant (Include ZIP Code)  IndusCo, Ltd. 2319 Joe Brown Dr. Greensboro, NC 27405  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label amendment to add new claims.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt.	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Cinda L. Bell	Title Agent for IndusCo, Ltd.	Telephone No. (Include Area Code) 703/494-6500; cbell@SciReg.com
<b>Certification</b> I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received <b>(Stamped)</b>
2. Signature <i>Cinda L. Bell</i>	3. Title Agent for IndusCo, Ltd.	
4. Typed Name Cinda L. Bell	5. Date 2/8/18	

**Loretta Forey**

---

**From:** notification@pay.gov  
**Sent:** Thursday, February 08, 2018 9:52 AM  
**To:** Loretta Forey  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 267LF6N0  
Agency Tracking ID: 75419449187  
Transaction Type: Sale  
Transaction Date: 02/08/2018 09:51:36 AM EST

Account Holder Name: James Damico

Transaction Amount: \$3,831.00  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*1000

Registration Number: 53053-27  
Company Name: INDUSCO, LTD.  
Company Number: 53053  
Action Code: A570

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

S: 1015476

Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 53053 INDUSCO LTD

Fee For Service: ☐ Yes ☒ No  
Billable: ☐ Yes ☒ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 21

Product #: 53053-27

Product Name: ENVIROSYSTEMS PROSHIELD 2551 D

Me Too  
Section 3:

Me Too Product  
Name:

Application Date: 05-Feb-2015



OPP Rec'd Date: 05-Feb-2015



Receipt Content

De ☐

Front End Date: 05-Feb-2015



Risk Manager Send Date:



Study

FFS Due Date:

Negotiated Due Date:

Paper Label

line

OPP Target Date:

res



/view/Edit

Receipt Description:

NEW AMENDMENT WITH STUDIES



**Fee for Service**

{1015476}~

This package includes the following

- ☐ New Registration
- ☒ Amendment

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

✓ Studies?      Fee Waiver?

volpay    % Reduction: \_\_\_\_\_

Risk Mgr.    **31**

Receipt No.

S-

**1015476**

EPA File Symbol/Reg. No.

**53053-27**

Pin-Punch Date:

**2/8/2018**

This item is NOT subject to FFS action.

Action Code:

Requested: **A570**

Granted: **A570**

Amount Due: \$ **3831**

Parent/Child Decisions:

Inert Cleared for Intended Use

Uncleared Inert in Product

Reviewer: A. Heffernan

Date: 2/9/18

Remarks:

PRIA label amendment



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 2-8-18

Experts In-Processing Signature: BB Date 2-14-18 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>53053-27</u>		EPA Receipt Date: <u>2-8-18</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)				X
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>N/A</u>	yes	no		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		X		
5	a) Selective Method (Fee category experts use)	yes	no		
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)		X		
7	Is the data package consistent with PR Notice 86-5		X		
8	Notice of Filing included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

\* Documentation: Pass  
- Required forms are complete

\* Inerts: N/A  
- No inerts to review

\* PR 11-3: Pass  
- MRID: 505238

\* Overall Status: Pass

Q0 2/22/18

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## A570 - Label amendment requiring data submission

- Must submit Group A and B product chemistry data to support a change in the manufacturing process
- Addition of public health pests requires efficacy data.
- Change in signal word requires acute toxicity data be submitted and/or referenced.
- Change from a registered to an unregistered source.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	X		
830.1600	Description of materials used to produce the product	X		
830.1650	Description of formulation process	X		
830.1670	Discussion on the formation of impurities	X		
830.1700	Preliminary analysis	X		
830.1750	Certified limits (158.345)	X		
830.1800	Enforcement analytical method	X		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	X		
830.6303	Physical State	X		
830.6304	Odor	X		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	N/A		
830.6315	Flammability	X		
830.6316	Explosibility	N/A		
830.6317	Storage stability*	X		
830.6319	Miscibility	N/A		
830.6320	Corrosion Characteristics*	X		
830.6321	Dielectric Breakdown Voltage	N/A		
830.7000	pH	X		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	X		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	X		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

\*May not be included with initial application

## A570 – Acute Toxicity Requirements

- Change in signal word requires acute toxicity data be submitted and/or referenced.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		X		
830.1200	Acute Dermal (LD50)		x		
830.1300	Acute Inhalation (LC50)		x		
830.2400	Acute Eye Irritation		x		
830.2500	Acute Dermal Irritation		X		
830.2600	Dermal Sensitization		X		

## Ohanyerenwa, Quenette

---

**From:** Cinda Bell <[cbell@scireg.com](mailto:cbell@scireg.com)>  
**Sent:** Thursday, February 22, 2018 8:56 AM  
**To:** Ohanyerenwa, Quenette  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Good morning,

This doesn't make sense. The AOAC germicidal spray test would not be submitted to support the dielectric breakdown voltage (830.6321) data requirement. Further, our records indicate that the AOAC germicidal spray test was submitted under MRID No. 45347601 and the dielectric breakdown voltage is not required for this product. There appears to be something incorrect in EPA's records. Please confirm.

Kind regards,  
Cinda

**From:** Ohanyerenwa, Quenette [<mailto:ohanyerenwa.quenette@epa.gov>]  
**Sent:** Thursday, February 22, 2018 8:42 AM  
**To:** Cinda Bell  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

AOAC Germicidal Spray Method

**From:** Cinda Bell [<mailto:cbell@scireg.com>]  
**Sent:** Wednesday, February 21, 2018 1:40 PM  
**To:** Ohanyerenwa, Quenette <[ohanyerenwa.quenette@epa.gov](mailto:ohanyerenwa.quenette@epa.gov)>  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

What is the title of the MRID number?

Thanks,  
Cinda

**From:** Ohanyerenwa, Quenette [<mailto:ohanyerenwa.quenette@epa.gov>]  
**Sent:** Wednesday, February 21, 2018 1:08 PM  
**To:** Cinda Bell  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Yes, this is the MRID that we have.

**From:** Cinda Bell [<mailto:cbell@scireg.com>]  
**Sent:** Wednesday, February 21, 2018 10:03 AM  
**To:** Ohanyerenwa, Quenette <[ohanyerenwa.quenette@epa.gov](mailto:ohanyerenwa.quenette@epa.gov)>  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Hi,

This MRID number does not exist in NPIRS. Are you sure this is correct?

Kind regards,  
Cinda



**From:** Ohanyerenwa, Quenette [<mailto:ohanyerenwa.quenette@epa.gov>]  
**Sent:** Wednesday, February 21, 2018 9:52 AM  
**To:** Cinda Bell  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Good morning!

It is MRID: 505238

It is the EPA Form 8570-35 if that helps. Thanks!

Quenette

**From:** Cinda Bell [<mailto:cbell@scireg.com>]  
**Sent:** Wednesday, February 21, 2018 9:50 AM  
**To:** Ohanyerenwa, Quenette <[ohanyerenwa.quenette@epa.gov](mailto:ohanyerenwa.quenette@epa.gov)>  
**Subject:** RE: Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Hi Quenette,

I do not know what MRID No. corresponds to this data requirement. Can you provide this information so that I can confirm?

Kind regards,  
Cinda

**From:** Ohanyerenwa, Quenette [<mailto:ohanyerenwa.quenette@epa.gov>]  
**Sent:** Tuesday, February 20, 2018 1:27 PM  
**To:** Cinda Bell  
**Subject:** Submission to EPA: EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27)

Good day,

My name is Quenette Ohanyerenwa and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product EnviroSystems Proshield 3651 D (EPA Reg. No. 53053-27). We have found a deficiency with the submission that will need to be addressed:

1. The Data Matrix you provided is missing the following guideline. Please provide an updated data matrix providing information about its status:
  - 830.6321: Dielectric Breakdown Voltage

Please send the revised data matrix before Feb 23rd so that we may further process your submission. After Feb 23rd, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Regards,  
Quenette Ohanyerenwa

Contractor, US EPA  
2777 S. Crystal Drive, S-4812

Arlington, VA 22202

(703) 347-0201

Email: [ohanyerenwa.quenette@epa.gov](mailto:ohanyerenwa.quenette@epa.gov)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 13, 2018

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-538238  
EPA File Symbol or Registration Number: 53053-27  
Product Name: ENVIROSYSTEMS PROSHIELD 3651 D  
EPA Receipt Date: 08-Feb-2018  
EPA Company Number: 53053  
Company Name: INDUSCO LTD

MS. CINDA L. BELL  
SCIREG, INC.  
INDUSCO LTD  
12733 DIRECTOR'S LOOP  
WOODBIDGE, VA 22192-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

A handwritten signature in black ink, appearing to be "JCL" or similar, written over a horizontal line.

Front End Processing Staff  
Information Technology & Resources Management Division

**SciReg, Inc.**  
Science and Regulatory Consultants

50523800

February 8, 2018

Mr. Eric Miederhoff  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: Label Amendment  
- EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27)

Dear Mr. Miederhoff:

On behalf of IndusCo, Ltd., SciReg, Inc. is submitting AOAC Germicidal Spray Method data to add *Pseudomonas aeruginosa* claims to the EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27) label. Additional claims and uses are also being added. Two copies of the label, one with the changes clearly marked, are attached.

This regulatory action falls under PRIA Category A570 – Label amendment requiring data review. The corresponding PRIA fee is \$3,831.00. A copy of the fee payment receipt is also enclosed.

If you have any questions, please contact me at 703-494-6500 or cbell@SciReg.com.

Sincerely,

*Cinda L. Bell*

Cinda L. Bell, MS  
Regulatory Specialist

Enclosures

## TRANSMITTAL DOCUMENT

### Submitter

IndusCo, Ltd.  
2319 Joe Brown Dr.  
Greensboro, NC 27405

SciReg, Inc. \*  
12733 Director's Loop  
Woodbridge, VA 22192

\* SciReg, Inc. is the authorized agent for IndusCo, Ltd.

### Regulatory action in support of which this package is submitted

Label Amendment: EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27)

### Transmittal Date

February 8, 2018

### Contents

Volume 1      Administrative Materials

Volume 2      AOAC Germicidal Spray Method (OSCPP 810.2200)

50523801

Company Official:      Cinda L. Bell      Cinda L. Bell 2/8/18

Company Name:      SciReg, Inc.

Company Contact:      Cinda L. Bell (703) 494-6500; cbell@SciReg.com



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

February 09, 2018

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

SCIREG, INC.  
INDUSCO LTD  
12733 DIRECTOR'S LOOP  
WOODBIDGE, VA 22192

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 08-FEB-18. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

S: 1015478

Milestone Email:

Regulatory Type: Product Registration - Section 3

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☐ Yes ☒ No

Tracking

Company: 53053 INDUSCO LTD

V

Risk Manager: Antimicrobials Division, Risk Management Team 21

Product #: 53053-27

Product Name: ENVIROSHIELD PROSHIELD 3851 D

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Me Too  
Section 3:

Me Too Product  
Name:

Application Date: 08-Feb-2013



OPP Rec'd Date: 08-Feb-2013



Receipt Content

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Front End Date: 08-Feb-2013



Risk Manager Send Date:



Study:

FFS Due Date:

Negotiated Due Date:

Paper Label

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OPP Target Date:

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View/Edit

Receipt Description:

NEW AMENDMENT WITH STUDIES



**SciReg, Inc.**  
Science and Regulatory Consultants

50523800

February 8, 2018

Mr. Eric Miederhoff  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: Label Amendment  
- EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27)

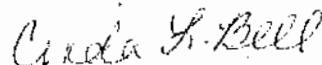
Dear Mr. Miederhoff:

On behalf of IndusCo, Ltd., SciReg, Inc. is submitting AOAC Germicidal Spray Method data to add *Pseudomonas aeruginosa* claims to the EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27) label. Additional claims and uses are also being added. Two copies of the label, one with the changes clearly marked, are attached.

This regulatory action falls under PRIA Category A570 – Label amendment requiring data review. The corresponding PRIA fee is \$3,831.00. A copy of the fee payment receipt is also enclosed.

If you have any questions, please contact me at 703-494-6500 or cbell@SciReg.com.

Sincerely,



Cinda L. Bell, MS  
Regulatory Specialist

Enclosures



## TRANSMITTAL DOCUMENT

### Submitter

IndusCo, Ltd.  
2319 Joe Brown Dr.  
Greensboro, NC 27405

SciReg, Inc. \*  
12733 Director's Loop  
Woodbridge, VA 22192

\* SciReg, Inc. is the authorized agent for IndusCo, Ltd.

### Regulatory action in support of which this package is submitted

Label Amendment: EnviroSystems ProShield 3651 D (EPA Reg. No. 53053-27)

### Transmittal Date

February 8, 2018

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Volume 1     Administrative Materials

Volume 2     AOAC Germicidal Spray Method (OSCPP 810.2200)

50523801

Company Official:     Cinda L. Bell     Cinda L. Bell 2/8/18

Company Name:     SciReg, Inc.

Company Contact:     Cinda L. Bell (703) 494-6500; cbell@SciReg.com

## **Memorandum**

Date: 02 / 09 / 18

To: pm 31, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission

**21-Day Screen of Amendment**  
**(Completed by Contractor)**

21-day Expires on 3-1-18

Document Part Of: 53053-27  
MRID, If Any: 505238

Content Screen: Recommended to  
☒ Pass/Fail

11-3 Review: ☒ Passed/Failed/NA

Overall Status: ☒ Pass/Fail

Document returned to:

ERIC MIEDERHOFF



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 31, 2016

Cinda L. Bell  
Agent (SciReg, Inc.)  
IndusCo, Ltd.  
2319 Joe Brown Drive  
Greensboro, NC 27405

Subject: Notification per PRN 98-10 -- Change Primary Brand Name  
Product Name: AM 3651 PI  
EPA Registration Number: 53053-26  
Application Date: August 23, 2016  
Decision Number: 520835

Dear Ms. Bell,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The primary brand name "EnviroSystems ProShield 3651 I" has replaced "AM 3651 PI" in the product record.

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at [daniels.joseph@epa.gov](mailto:daniels.joseph@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Miederhoff", with a stylized flourish at the end.

for

Eric Miederhoff, Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

**SciReg, Inc.**  
Science and Regulatory Consultants

August 22, 2016

Mr. Eric Miederhoff  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

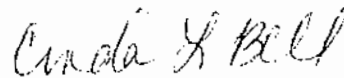
Re: Notification per PR Notice 98-10: Primary Brand Name  
- AM 3651 PI (EPA Reg. No. 53053-26)

Dear Mr. Miederhoff:

On behalf of IndusCo, Ltd. (EPA Co. No. 53053), SciReg, Inc. is submitting a notification per PR Notice 98-10 to change the primary brand name for AM 3651 PI (EPA Reg. No. 53053-26) to EnviroSystems ProShield 3651 I. One copy of the label, with the changes clearly marked, is attached. No other changes have been made to the label.

If you have any questions, please contact me at 703-494-6500 or cbell@SciReg.com.

Sincerely,



Cinda L. Bell, MS  
Regulatory Specialist

Enclosures



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 53053-26	2. EPA Product Manager Eric Miederhoff	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AM 3651 PI	PM# 31	
5. Name and Address of Applicant (Include ZIP Code)  IndusCo, Ltd. 2319 Joe Brown Drive Greensboro, NC 27405  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of change in primary brand name per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. Per Container If "Yes" Package wgt. No. Per Container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Cinda L. Bell		Title Agent		Telephone No. (Include Area Code) 703-494-6500; cbell@SciReg.com	
<b>Certification</b> I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Cinda L. Bell</i>		3. Title Agent (SciReg, Inc.)			
4. Typed Name Cinda L. Bell		5. Date 8/23/16			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 08, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MS. CINDA L. BELL  
SCIREG, INC., AGENT FOR  
INDUSCO, LTD.  
12733 DIRECTOR'S LOOP  
WOODBIDGE, VA 22192

Dear Ms. Bell:

Subject: Transfer of Pesticide Registrations and Data From Company Number 70871 to Company Number 53053

Pursuant to your request in your letter and transfer agreement of November 10, 2015, we have approved the transfer of the following registrations from **INHOLD, LLC**, company number **70871** to **INDUSCO, LTD.**, company number **53053**.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
BIOSHIELD AM 500 I	70871-16	53053-21
BST PROTECTANT CONCENTRATE C15	70871-17	53053-22
BST PROTECTANT RTU 50	70871-18	53053-23
BST PROTECTANT RTU 75	70871-19	53053-24
BIOSHIELD BSTI 1860	70871-20	53053-25
AM 3651P1	70871-21	53053-26
AN 3651P	70871-22	53053-27
BIOSHIELD AM 500	70871-23	53053-28

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months,

any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product." EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.



Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

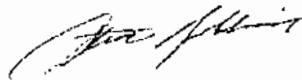
By copy of this letter we are informing the transferor of these changes. If you have any questions, please contact Louis Vaughn at (703) 308-8114.

The Agency acknowledges it has received a request for data transfer dated November 10, 2015 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **INDUSCO, LTD.** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief  
Information Services Branch  
Information Technology & Resource Management Div. (7504P)

cc: MS. CINDA L. BELL  
SCIREG, INC., AGENT FOR  
INHOLD, LLC  
12733 DIRECTOR'S LOOP  
WOODBIDGE, VA 22192

RE: L\_70871\_RAD\_53053\_02\_08\_2016

Appendix A

List of Inhold, LLC Data Submitted to EPA

MRID NO.	CITATION	SUBMITTER	SUBMISSION DATE	EXCLUSIVE USE (YES/NO)
44279400	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Applications for Registration for AM 500 I and AM 500. Transmittal of 4 Studies.	INHOLD, LLC	May 19, 1997	No
44279401	BioShield Technologies, Inc. (1997) Product Identity and Composition of AM 500 I and AM 500. Unpublished study. 14 p.	INHOLD, LLC	May 19, 1997	No
44279402	BioShield Technologies, Inc. (1997) Description of Beginning Materials and the Manufacturing Process of AM 500 I and AM 500. Unpublished study. 24 p.	INHOLD, LLC	May 19, 1997	No
44279403	Berkner, J. (1997) Discussion of Formation of Impurities in AM 500 I and AM 500. Unpublished study prepared by BioShield Technologies, Inc. 4 p.	INHOLD, LLC	May 19, 1997	No
44279404	Wells, D. (1997) AM500--Conducting Product Chemistry Studies for an End-Use Product Following Product Properties Test Guidelines: Final Report: Lab Project Number: 97-3-6913; 13637.1196.6100.880. Unpublished study prepared by Springborn Laboratories, Inc. 44 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7300, 830.7100, & 830.7000}	INHOLD, LLC	May 19, 1997	No
44351900	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Applications for Registration for BioShield AM 500 and BioShield AM 500 I. Transmittal of 1 Study.	INHOLD, LLC	August 18, 1997	No
44351901	Jellinek, Schwartz & Connolly, Inc. (1997) Preliminary Analysis, Certification of Ingredient Limits, and Analytical Method for Enforcement of Limits for BioShield AM 500 and BioShield AM 500 I: Lab Project Number: 3637.0497.6102.250; 102196/830.6317/BIOSHIELD. Unpublished study prepared by Springborn Laboratories, Inc. 13 p.	INHOLD, LLC	August 18, 1997	No
44376000	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Protectant Concentrate C15. Transmittal of 3 Studies.	INHOLD, LLC	September 15, 1997	No
44376001	BioShield Technologies, Inc. (1997) Product Identity of BST Protectant Concentrate C15. Unpublished study. 23 p.	INHOLD, LLC	September 15, 1997	No
44376002	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Protectant Concentrate C15: Lab Project Number: 102196/830.6317/BIOSHIELD. Unpublished study. 11 p.	INHOLD, LLC	September 15, 1997	No
44376003	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Protectant Concentrate C15. Unpublished study. 4 p.	INHOLD, LLC	September 15, 1997	No

# Appendix A

## List of Inhold, LLC Data Submitted to EPA

44376200	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Registration of BST Protectant 50. Transmittal of 3 Studies.	INHOLD, LLC	September 15, 1997	No
44376201	BioShield Technologies, Inc. (1997) Product Identity of BST Protectant 50. Unpublished study. 23 p.	INHOLD, LLC	September 15, 1997	No
44376202	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Protectant 50. Unpublished study. 11 p.	INHOLD, LLC	September 15, 1997	No
44376203	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Protectant 50. Unpublished study. 4 p.	INHOLD, LLC	September 15, 1997	No
44379400	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of Application for the Registration of BST Protectant 75. Transmittal of 3 Studies.	INHOLD, LLC	September 15, 1997	No
44379401	BioShield Technologies, Inc. (1997) Product Identity of BST Protectant 75. Unpublished study. 23 p.	INHOLD, LLC	September 15, 1997	No
44379402	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Protectant 75. Unpublished study. 11 p.	INHOLD, LLC	September 15, 1997	No
44379403	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Protectant 75. Unpublished study. 4 p.	INHOLD, LLC	September 15, 1997	No
44385100	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Kleen Air 05. Transmittal of 3 Studies.	INHOLD, LLC	September 23, 1997	No
44385101	BioShield Technologies, Inc. (1997) Product Identity of BST Kleen Air 05. Unpublished study. 31 p.	INHOLD, LLC	September 23, 1997	No
44385102	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Kleen Air 05: Lab Project Number: 102196/830.6317/BIOSHIELD. Unpublished study. 12 p.	INHOLD, LLC	September 23, 1997	No
44385103	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Kleen Air 05. Unpublished study. 4 p.	INHOLD, LLC	September 23, 1997	No
44385200	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Fabric Softener 175. Transmittal of 3 Studies.	INHOLD, LLC	September 22, 1997	No
44385201	BioShield Technologies, Inc. (1997) Product Identity of BST Fabric Softener 175. Unpublished study. 67 p.	INHOLD, LLC	September 22, 1997	No
44385202	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Fabric Softener 175. Unpublished study. 12 p.	INHOLD, LLC	September 22, 1997	No

Appendix A

List of Inhold, LLC Data Submitted to EPA

44385203	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Fabric Softener 175. Unpublished study. 4 p.	INHOLD, LLC	September 22, 1997	No
44385300	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Carpet and Upholstery Cleaner Aerosol 25. Transmittal of 3 Studies.	INHOLD, LLC	September 22, 1997	No
44385301	BioShield Technologies, Inc. (1997) Product Identity of BST Carpet and Upholstery Cleaner Aerosol 25. Unpublished study. 41 p.	INHOLD, LLC	September 22, 1997	No
44385302	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Carpet and Upholstery Cleaner Aerosol 25. Unpublished study. 11 p.	INHOLD, LLC	September 22, 1997	No
44385303	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Carpet and Upholstery Cleaner Aerosol 25. Unpublished study. 4 p.	INHOLD, LLC	September 22, 1997	No
44385600	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Mold and Mildew Remover and All Purpose Cleaner 25. Transmittal of 3 Studies.	INHOLD, LLC	September 23, 1997	No
44385601	BioShield Technologies, Inc. (1997) Product Identity of BST Mold and Mildew Remover & All Purpose Cleaner 25. Unpublished study. 68 p.	INHOLD, LLC	September 23, 1997	No
44385602	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Mold and Mildew Remover & All Purpose Cleaner 25. Unpublished study. 12 p.	INHOLD, LLC	September 23, 1997	No
44385603	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Mold and Mildew Remover & All Purpose Cleaner 25. Unpublished study. 4 p.	INHOLD, LLC	September 23, 1997	No
44385700	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Carpet and Upholstery Concentrate C15. Transmittal of 3 studies.	INHOLD, LLC	September 22, 1997	No
44385701	BioShield Technologies, Inc. (1997) Product Identity of BST Carpet and Upholstery Cleaner Concentrate C15. Unpublished study. 47 p.	INHOLD, LLC	September 22, 1997	No
44385702	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Carpet and Upholstery Cleaner Concentrate C15: Lab Project Number: 102196/830.6317/BIOSHIELD. Unpublished study. 12 p.	INHOLD, LLC	September 22, 1997	No
44385703	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Carpet and Upholstery Cleaner Concentrate C15. Unpublished study. 4 p.	INHOLD, LLC	September 22, 1997	No

# Appendix A

## List of Inhold, LLC Data Submitted to EPA

44386000	BioShield Technologies, Inc. (1997) Submission of Product Chemistry Data in Support of the Application for Registration of BST Carpet and Upholstery Cleaner 25. Transmittal of 3 Studies.	INHOLD, LLC	September 22, 1997	No
44386001	BioShield Technologies, Inc. (1997) Product Identity of BST Carpet and Upholstery Cleaner 25. Unpublished study. 37 p.	INHOLD, LLC	September 22, 1997	No
44386002	BioShield Technologies, Inc. (1997) Certification of Limits and Analytical Method for Enforcement of Limits for BST Carpet and Upholstery Cleaner 25: Lab Project Number: 102196/830.6317/BIOSHIELD. Unpublished study. 11 p.	INHOLD, LLC	September 22, 1997	No
44386003	BioShield Technologies, Inc. (1997) Physical and Chemical Properties of BST Carpet and Upholstery Cleaner 25. Unpublished study. 4 p.	INHOLD, LLC	September 22, 1997	No
44553500	BioShield Technologies, Inc. (1998) Submission of Toxicity Data in Support of the Application for Registration of BioShield AM 500 and BioShield 500 I. Transmittal of 1 Study.	INHOLD, LLC	May 7, 1998	No
44553501	Kuhn, J. (1998) Primary Eye Irritation Study in Rabbits: AM500: Final Report: Lab Project Number: 4263-98. Unpublished study prepared by Stillmeadow Inc. 21 p.	INHOLD, LLC	May 7, 1998	No
44789800	BioShield Technologies, Inc. (1999) Submission of Toxicity Data in Support of the Application for Registration of BST Protectant 50. Transmittal of 1 Study.	INHOLD, LLC	March 30, 1999	No
44789801	Kuhn, J. (1999) Primary Eye Irritation Study in Rabbits: AM 500: Final Report: Lab Project Number: 4842-98. Unpublished study prepared by Stillmeadow, Inc. 17 p. {OPPTS 870.2400}	INHOLD, LLC	March 30, 1999	No
44789900	BioShield Technologies, Inc. (1999) Submission of Toxicity Data in Support of the Application for Registration of BST Protectant Concentrate C15. Transmittal of 1 Study.	INHOLD, LLC	March 30, 1999	No
44789901	Kuhn, J. (1999) Primary Eye Irritation Study in Rabbits: (BST Protectant Concentrate C15): Final Report: Lab Project Number: 4841-98. Unpublished study prepared by Stillmeadow, Inc. 17 p. {OPPTS 870.2400}	INHOLD, LLC	March 30, 1999	No
44876600	BioShield Technologies, Inc. (1999) Submission of Product Chemistry Data in Support of the Application for Registration of BioShield AMS 1860. Transmittal of 3 Studies.	INHOLD, LLC	July 19, 1999	No
44876601	Wells, D. (1999) AMS 1860-Preliminary Analysis: Lab Project Number: 13637.6119: 4.3.07(2). Unpublished study prepared by Springborn Laboratories, Inc. 51 p. {OPPTS. 830.1700}	INHOLD, LLC	July 19, 1999	No
44876602	Damico, J. (1999) AMS 1860-Certified Limits. Unpublished study prepared by BioShield Technologies, Inc. 4 p. {OPPTS. 830.1750}	INHOLD, LLC	July 19, 1999	No

# Appendix A

## List of Inhold, LLC Data Submitted to EPA

44876603	Wells, D. (1999) AMS 1860-Product Chemistry Testing for an End-Use Product Following Product Properties Test Guidelines, Series 830: Lab Project Number: 13637.6118. Unpublished study prepared by Springborn Laboratories, Inc. 47 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6315, 830.7300, 830.7100, 830.7000}	INHOLD, LLC	July 19, 1999	No
44885900	Bioshield Technologies, Inc. (1999) Submission of Product Chemistry Data in Support of the Application for Registration of Bioshield AMS 1860. Transmittal of 2 Studies.	INHOLD, LLC	July 19, 1999	No
44885901	Damico, J. (1999) Product Identity and Disclosure of Ingredients, Description of Beginning Materials and Manufacturing Process, and Discussion of the Formation of Impurities: AMS-1860. Unpublished study prepared by SciReg, Inc. 73 p. {OPPTS 830.1550, 830.1620, 830.1670}	INHOLD, LLC	July 19, 1999	No
44885902	Wells, D. (1999) AMS 1860--Determination of the Boiling Point: Lab Project Number: 13637.6120. Unpublished study prepared by Springborn Laboratories. 25 p. {OPPTS 830.7200}	INHOLD, LLC	July 19, 1999	No
44929100	BioShield Technologies, Inc. (1999) Submission of Product Chemistry Data in Support of the Application for Registration of AMS 1860. Transmittal of 1 Study.	INHOLD, LLC	September 23, 1999	No
44929101	Ward, T.; Rondon, C.; Boeri, R. (1999) AMS 1860: Determination of Stability at Normal and Elevated Temperatures and in the Presence of Metals and Metal Ions: Lab Project Number: 1853-BS. Unpublished study prepared by T.R. Wilbury Labs., Inc. 40 p. {OPPTS 830.6313}	INHOLD, LLC	September 23, 1999	No
44972400	BioShield Technologies, Inc. (1999) Submission of Product Chemistry Data in Support of the Application for Registration of BSTI 1860. Transmittal of 1 Study.	INHOLD, LLC	November 18, 1999	No
44972401	Damico, J. (1999) BSTI 1860: Product Identity and Disclosure of Ingredients, Description of Beginning Materials and Manufacturing Process, and Discussion of the Formation of Impurities. Unpublished study prepared by SciReg, Inc. 43 p. {OPPTS 830.1550, 830.1620, 830.1620, 830.1670, 830.1750}	INHOLD, LLC	November 18, 1999	No
45121300	BioShield Technologies, Inc. (2000) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of AM 3651PI. Transmittal of 8 Studies.	INHOLD, LLC	May 10, 2000	No

Appendix A

List of Inhold, LLC Data Submitted to EPA

45121301	Smith, F. (2000) AM 3651P1: Product Identity and Composition, Description of Beginning Materials, Description of Formula Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 40 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750}	INHOLD, LLC	May 10, 2000	No
45121302	Wells, D. (1999) AM 3651P1--Determination of Storage Stability: Lab Project Number: 13637.0897.6107.865: 13637.6107. Unpublished study prepared by Springborn Labs., Inc. 36 p. {OPPTS 830.6317}	INHOLD, LLC	May 10, 2000	No
45121303	Kuhn, J. (1999) AM 3651P1: Acute Oral Toxicity Study in Rats: Final Report: Lab Project Number: 4850-98. Unpublished study prepared by Stillmeadow, Inc. 24 p. {OPPTS 870.1100}	INHOLD, LLC	May 10, 2000	No
45121304	Kuhn, J. (1999) AM 3651P1: Acute Dermal Toxicity Study in Rabbits: Final Report: Lab Project Number: 4851-98. Unpublished study prepared by Stillmeadow, Inc. 22 p. {OPPTS 870.1200}	INHOLD, LLC	May 10, 2000	No
45121305	Bennick, J. (1999) AM 3651P1: Acute Inhalation Toxicity Study in Rats: Final Report: Lab Project Number: 4852-98. Unpublished study prepared by Stillmeadow, Inc. 36 p. {OPPTS 870.2400}	INHOLD, LLC	May 10, 2000	No
45121306	Kuhn, J. (1999) AM 3651P1: Primary Dermal Irritation Study in Rabbits: Final Report: Lab Project Number: 4854-98. Unpublished study prepared by Stillmeadow, Inc. 13 p. {OPPTS 870.2400}	INHOLD, LLC	May 10, 2000	No
45121307	Kuhn, J. (1999) AM 3651P1: Primary Dermal Irritation Study in Rabbits: Final Report: Lab Project Number: 4854-98. Unpublished study prepared by Stillmeadow, Inc. 13 p. {OPPTS 870.2500}	INHOLD, LLC	May 10, 2000	No
45121308	Kuhn, J. (1999) AM 3651P1: Dermal Sensitization Study in Guinea Pigs: Final Report: Lab Project Number: 4855-98. Unpublished study prepared by Stillmeadow, Inc. 18 p. {OPPTS 870.2600}	INHOLD, LLC	May 10, 2000	No
45245700	BioShield Technologies, Inc. (2000) Submission of Product Chemistry Data in Support of the Application for Registration of AM 3651P1. Transmittal of 1 Study.	INHOLD, LLC	September 20, 2000	No
45245701	Damico, J. (2000) AM 3651P1: Physical-Chemical Characteristics. Unpublished study prepared by SciReg, Inc. 7 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.7000, 830.7100, 830.7300, 830.6315, 830.6320}	INHOLD, LLC	September 20, 2000	No
45347600	Bioshield Technologies, Inc. (2001) Submission of Efficacy Data in Support of the Application for Registration AM 3651P1. Transmittal of 2 Studies.	INHOLD, LLC	March 2, 2001	No

# Appendix A

## List of Inhold, LLC Data Submitted to EPA

45347601	Snyder, A. (1999) AOAC Use-Dilution Method: AM 3651P: Final Study Report: Lab Project Number: 7361/SRC021099.UD: 7669/SRC061099.UD. Unpublished study prepared by ViroMed Biosafety Labs. 15 p.	INHOLD, LLC	March 2, 2001	No
45347602	Onstad, B. (2000) Germicidal and Detergent Sanitizing Action of Disinfectants: AM 3651P: Final Study Report: Lab Project Number: 7457: SRC050699.SAN. Unpublished study prepared by ViroMed Biosafety Labs. 10 p.	INHOLD, LLC	March 2, 2001	No



Please Read All Instructions Before Completing this Form (Form must be typed)

Form Approved. OMB. No. 2070-0044



United States  
**Environmental Protection Agency**  
 Office of Pesticide Programs (7505C)  
 Washington, DC 20460

### Notice of Supplemental Distribution of a Registered Pesticide Product

#### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

75497-8

Distributor Company Number

83142

**Note: Do not submit distributor product labels**

Name of Registered Product (Basic product name accepted by EPA)

Bioshield AM 3651P

Distributor Product Name

Biostat-Max

Name and Address of Distributor (Type, include ZIP code)

Advanced Remediation Solutions, Inc.  
 4880 Lower Roswell Road, Suite 165 #507  
 Marietta, GA 30068-4385

#### Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

#### Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

*Edna L. Johnson, Director*

Date

2/8/06

#### Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

*Edna L. Johnson, Director*

Date

2/8/06



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 14, 2007

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

TIMOTHY C. MOSES  
INTERNATIONAL BIOCHEMICAL INDUSTRIES, INC.  
4405 INTERNATIONAL BLVD., SUITE B-109  
NORCROSS, GA 30093

Dear Mr. Moses:

Subject: Transfer of Pesticide Registrations From Company Number 75497 to Company Number 70871

Pursuant to your request in your letter and transfer agreement of June 4, 2007, we have approved the transfer of the following registrations from **NOVA BIOGENETICS, INC.**, company number **75497** to **INTERNATIONAL BIOCHEMICAL INDUSTRIES, INC.**, company number **70871**.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
BIOSHIELD AM 500 I	75497-2	70871-16
BST PROTECTANT CONCENTRATE C15	75497-3	70871-17
BST PROTECTANT RTU 50	75497-4	70871-18
BST PROTECTANT RTU 75	75497-5	70871-19
BIOSHIELD BSTI 1860	75497-6	70871-20
AM 3651PI	75497-7	70871-21
AN 3651P	75497-8	70871-22
BIOSHIELD AM 500	75497-1	70871-23

You should indicate the new company designation, new EPA Registration Number and

new Establishment Number (it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Kathleen O'Malley at (703) 305-5411.

Sincerely,



Steve Robbins, Chief  
Information Services Branch  
Information Technology & Resource Management Div. (7504P)

cc: ED SCHWARTZ  
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